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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/736,728	12/14/2000	Mahendra S. Rao	UT-0030	7449

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/736,728	RAO ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *08 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-19 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-19 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/08/03 has been entered.

2. The rejection of claims 13-19 & 49 under 35 U.S.C. 102(e) as being anticipated by Jat et al. (U.S. Patent 5688692) is withdrawn due to the amendment of the claims to include a "positive immunoselection" step.

3. The rejection of claims 13-19 & 49 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements is withdrawn due to the amendment of the claims.

4. Applicant's arguments filed 9/08/03 have been fully considered but they are not deemed to be persuasive.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 13-19 & 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application is apparent for the recitation of "immunonegative for PDGF-α and PDGF-β", versus immunonegative for the PDGF-α and PDGF-β "receptors", "the Ran-2 antigen" and "the R24 anti-GD3 antibody", while being A2B5-positive, as alternatively described on pages 20-21 of the specification. In other words, giving an incomplete characterization of these cells by removing negative phenotypes increases the scope of that claimed, versus that disclosed on pages 5, 15-16, 23-24, 17-20, 27-30, 30-32 & 33 as argued by Applicants (whose page citations appear to be three pages off); thereby, constituting new matter.

7. Claims 13-19 & 49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jat (US Patent 5,688,692) in view of Gard et al., for the reasons made of record in Paper No: 11 (mailed 4/07/03), and as follows.

Applicants argue on pages 9-10 of the response that motivation, a reasonable expectation of success, and the "prior art references when combined must teach or suggest all claim limitations". The Examiner agrees. However, even though Applicants point out that some of Jat's cultures "looked like O-2A progenitors", these are not the only cells Jat reasonably used in his method of culturing/isolating/differentiating/obtaining glial cells, where the claims

alternatively still do not recite closed language (i.e., not "comprising"), nor recite a homogenous population of starting glial progenitor cells that excludes the O-2A progenitor- glial restricted precursor cells, nor recite an additional method step that does not reasonably flow from the teachings of Jat, in view of Gard. For example, Example 1 in the instant specification describes first the removal by negative immunoselection of cells expressing E-NCAM, which therefore, probably should be incorporated within the claims. Second, Table 4 and page 26 appear contradictory (again, note Applicants appear to be off three pages in their citations), in that no PGDFRβ expression exists for O-2A progenitors in Table 4. Third, since both O-2A progenitors and the instantly claimed glial progenitor cells (which also differentiate into oligodendrocytes as recited in claim 18) are all "glial progenitor cells", distinguishing characteristics still need to be incorporated into the claims and appropriately argued, in order to obviate this rejection. Thus, Applicants' arguments are not persuasive.

In summary, Jat et al. teach a method of obtaining and propagating a population of mammalian/E18 embryonic rat CNS glial precursor cells that are also differentiated into non-process bearing A2B5-GFAP+ astrocytes and A2B5+ oligodendrocytes in the presence of the factors, PDGF, bFGF (i.e., col. 25; as it relates to claims 13-14, 18-19 & 49), as well as in the presence of the factor, purified cortical astrocyte conditioned medium, which contains 10% fetal calf serum (i.e., col. 23, lines 47-54; as it relates to claims 14 & 15) that inherently also contains thyroid hormone (T3); absent evidence to the contrary (e.g., col. 25; as it relates to claims 18-19). In that Jat et al further disclose a method of differentiation of glial restricted precursors in the presence of bFGF and CNTF, process bearing A2B5+GFAP+ astrocytes are also reasonably produced in their method (i.e., col. 25; as it relates to claims 16-17), as claimed.

However, Jat et al do not teach positive or negative immunoselection/ immunopanning with specific antibodies.

Gard et al. teach a method of obtaining and propagating rat cerebral progenitor cells (e.g., G_{D3+}O4- and GFAP+ CNS glial progenitor cells) in BDM minimal salt medium containing 0.5% fetal calf serum (FBS) which inherently contains PDGF and FGF; absent evidence to the contrary (i.e., pgs. 597-598; as it relates to claim 49). Gard teach the method of switching these cells upon culturing under differentiating conditions (i.e., in the presence of CNTF) to produce a stellate astrocytic/glial phenotype (i.e., inherently process bearing A2B5+GFAP+; pgs. 598, 2nd col.- pg. 600; Fig. 1 & 4 & Table 4; as it relates to claims 13 & 16-18). Differentiation of O4+ glial progenitor/precursor cells into oligodendrocytes is also disclosed by Gard using CNTF (e.g., pg. 600, col. 2- pg. 601; as it relates to claim 18). Differentiation of O4+ glial precursor cells into non-process bearing A2B5-GFAP+ astrocytes in the presence of fetal calf serum (FBS) is further disclosed on pages 601-602 (i.e., as it relates to claims 13-15). Lastly, Gard teach immunopanning as a method of selecting for distinct populations of glial progenitor/precursor cells (e.g., pg. 597). However, Gard et al. do not teach using A2B5 antibodies to isolate glial precursor cells.

It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to initially obtain a pure homogenous population of Jat's glial progenitor cells before differentiating these progenitor cells to various populations of glial cells, as disclosed by both Gard et al. and Jat et al., using Gard's method of immunopanning with Jat's A2B5 antibody, because Gard et al. teach that immunopanning is a technique to "compare, in culture challenges with different... inducing agents, the differentiation potential of ... progenitors isolated directly

from early postnatal... forebrain" (e.g., see pg. 597; 1st column). In other words, the differentiation potential of glial precursor cells to different and distinct glial cell populations using specific growth factors, as described by both Jat and Gard, is more accurately determined using homogenous populations of cells initially, by definition.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCH

Robert C. Hayes, Ph.D.
January 6, 2003
Pat. Sg.
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